Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

Assessment the effect of The Heel Protective Device on the incidence and severity of pressure ulcer in elderly hospitalized patients with lower limbs fracture

Protocol summary

Study aim
Determining the effect of using heel support device on reducing the incidence and severity of pressure ulcers in the elderly with a lower limb fracture

Design
Clinical trials with a control group, non - blindness, randomized in Permuted block method

Settings and conduct
the research community of the elderly is a way of lower organ fracture, which is in the orthopedic parts of the Kamyab hospital. After selecting the Individuals who have entrance criteria, samples will be divided randomly into two groups of intervention and control groups. The intervention group will be used by heels supporting the patient's legs and reducing the pressure applied on the heel of the leg for three days. The heel support device will be made and used during the study. In the control group, routine actions will be performed, as it will be used from a pillow or roll blanket underneath the patient's leg and will be checked on a daily basis using a checklist of skin health assessment.

Participants/Inclusion and exclusion criteria
AGE more than 60 - unilateral lower limb fracture- informed consent of participating in the study- consciousness - the lack of acute problems - the absence of acute diseases - braden scores less than 16 - lack of a sustained and traumatic brain injury in the lower limb

Intervention groups
intervention group:The mechanism made by the heel supporting the heel on the heels of the patient's legs and the reduction of pressure applied on the heel to check the incidence and severity of the pressure wound will be used for three days. control group:Routine actions are carried out, so that it will be used for three days from a pillow or roll blanket underneath the calf's leg.

Main outcome variables
the incidence and the severity of the heel pressure ulcer

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200727048225N1**
Registration date: **2020-10-24, 1399/08/03**
Registration timing: **registered_while_recruiting**

Last update: **2020-10-24, 1399/08/03**
Update count: **0**

Registration date
2020-10-24, 1399/08/03

Registrant information

Name
Saeedeh Mohammadi Saber

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3256 8674

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-10-22, 1399/08/01

Expected recruitment end date
2021-02-19, 1399/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Assessment the effect of The Heel Protective Device on the incidence and severity of pressure ulcer in elderly hospitalized patients with lower limbs fracture

Public title
Assessment the effect of The Heel Protective Device on the incidence of pressure ulcer

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Age over 60 years Unilateral lower limb fracture informed consent to participate in research

Exclusion criteria:
cognitive problems - Absence of - - Absence of acute diseases Braden score more than 16 pressure and traumatic ulcer in fractured lower limb

Age
From **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Permuted block method In our study, we will use the random allocation of the random - block or permutation method to ensure that exactly equal numbers of participants are entered into the category of intervention and control. Each block size can be 5, 10, 16 to 20. In this way, intervention is given to the first block and routine maintenance to the second and again the first type to a third block and so on. The randomization benefits of the block are that the balance of the number of participants in each group is guaranteed. The number of people in each group will never exceed half the number of people per block. The disadvantages of this type of randomizations are that statistical analysis in this type of segmentation is more complex and there is also a foreseeable danger that there is no difficulty in identifying the use of the vehicle, and the results will be reliable.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences

Street address
Daneshgah street

City
Mashhad

Province
Razavi Khorasan

Postal code
91388-13944

Approval date
2020-08-04, 1399/05/14

Ethics committee reference number
IR.MUMS.NURSE.REC.1399.041

Health conditions studied

1

Description of health condition studied
the heel pressure ulcer

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
the incidence of the heel pressure ulcer

Timepoint
before the intervention and for 3 days during the intervention

Method of measurement
Skin health assessment checklist (based on EPUAP pressure ulcer classification system)

2

Description
severity of the heel pressure ulcer

Timepoint
before the intervention and for 3 days during the intervention

Method of measurement
PUSH questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: in the intervention group the vehicle's supporting vehicle will be used for three days, and during this period it will be done for ten minutes for patients by caregivers or nurse. During one or two shifts the researcher will take two hours for ten minutes, ensuring that it will be reassured by either cell nurse or nurse. During the intervention of each day the pressure wound or the severity of the pressure wound in the soles of the foot and leg of the leg are examined using a check list of skin health assessment (redness, itching, and burn), as well as any allergy signs (redness, itching and burning), and change position with ease of use of the use of heels supporting heels and inclination to continue taking part in the study

Category

Prevention

2

Description

Control group: Routine actions will be performed, so that it will be used for three days from a pillow or roll blanket underneath the calf's leg.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Kamyab hospital

Full name of responsible person

Alireza mahmoudi gharaee

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Fadaeeiane Eslam Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Saeedeh Mohammadi Saber

Position

Master student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Full name of responsible person

Fatemeh Esmaelzadeh

Position

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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Only part of the data may be shared after identifying those related to the main outcome
When the data will become available and for how long
The beginning of the access period is 6 months after the results are published.
To whom data/document is available
Access is available only for practitioners working in academic and academic institutions
Under which criteria data/document could be used
The only analyses used in the study are allowed to be delivered on the data delivered
From where data/document is obtainable
mohammadis971@mums.ac.ir
What processes are involved for a request to access data/document
The data will be contacted by e - mail, and the relevant demand for e - mail is called the request and call number
Comments